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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/913,770 | 08/17/2001 | Takuya Watanabe | 46342-56401 | 4523 |

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| EXAMINER | |
|---|---|
| LOCKARD, JON MCCLELLAND | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/913,770 | WATANABE ET AL. | |
| | Examiner | Art Unit | |
| | Jon M Lockard | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *9-13, 15-18, and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 Aug 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *17 Aug 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicants' election with traverse of Group I, claims 1-8, 14, and 19-20 in the reply filed on 14 June 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

### *Status of Application, Amendments, And/Or Claims*

Applicants' amendments filed on 04 November 2002 and 27 May 2003 have been received and entered in full. Claims 1-27 are pending. Claims 1-8, 14, and 19-20 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

It is noted that this application appears to claim subject matter disclosed in prior Application No. 11/41336, 11/125765, and PCT/JP00/00927, filed 02/19/1999, 05/06/1999, and 02/18/2000 respectively. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120.

See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was

unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

### *Drawings*

The drawings are objected to because Figures 1 and 2 disclose nucleotide and amino acid sequences without the accompanying SEQ ID NO:. The SEQ ID NO: may be inserted into the figure or the Brief Description of the Drawings. A proposed drawing correction or corrected drawings are required in reply to the Office Action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Therefore, it is unnecessarily redundant to repeat the sequence information in the form of Figures. Applicants should amend the specification to delete any Figures (e.g. Figures 1 and 2) which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

### *Information Disclosure Statement*

The Information Disclosure Statement (IDS) submitted on 17 Aug 2001 has been considered by the Examiner.

### *Specification*

The abstract of the disclosure is objected to because it is too long and more than one paragraph in length. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The Claims should be the object of a sentence starting with "(I or We) claim", "The invention claimed is," or the equivalent. See M.P.E.P. 608.01(m).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant is requested to avoid the use of "novel" in the title, as patents are presumed to be novel and unobvious.

### *Claim Rejections - 35 USC § 101 and 35 USC §112*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-8, 14, and 19-20 are drawn to a protein of SEQ ID NO:1 and a polynucleotide encoding the protein, all of which are unaltered, naturally occurring compounds. Thus, they are not articles of "manufacture". These rejections may be obviated by amending the claims to read "an isolated protein", "an isolated partial peptide", and "an isolated polynucleotide", so long as there is support for the amendment in the specification.

Claims 1-8, 14, and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility.

The instant application discloses a protein comprising SEQ ID NO:1 or its homologues, polynucleotides encoding the proteins, a method of producing the proteins, and a method of determining a ligand to the proteins. The specification asserts that the instant application relates to a G protein coupled receptor (GPCR) derived from the human hippocampus (see page 5, lines 13-17). The specification discloses a hydrophobicity plot based on the deduced amino acid

sequence set forth in SEQ ID NO:1. However, the instant specification does not teach any physiologic ligands or functional characteristics of the GPCR set forth in SEQ ID NO:1 or encoded by the disclosed nucleic acid set forth in SEQ ID NO:2. Further, the GPCR comprising SEQ ID NO:1 or encoded by said disclosed nucleic acid has never been expressed in a cell or organism or assayed for functional activity. The amino acid for set forth in SEQ ID NO:1 has been deduced from the nucleic acid sequence (see page 14, lines 4-10; Figures 2 and 3). There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

The specification asserts the following as patentable utilities for the claimed receptor protein and partial peptides of SEQ ID NO:1 and the DNA encoding the receptor protein or the partial peptides:

1) in searching for ligands to the GPCR protein (pg 47, lines 1-3);

2) prophylactic and/or therapeutic agents for diseases associated with dysfunction of the GPCR protein of the present invention or it partial peptides (pg 47, lines 3-6);

3) as agents for gene diagnosis (pg 47, line 6);

4) in methods of screening compounds that alter the expression level of the receptor protein of the present invention or its partial peptides (pg 47, lines 7-9);

5) prophylactic and/or therapeutic agents for various diseases comprising a compound that alters the expression level of the receptor protein of the present invention or its partial peptides (pg 47, lines 10-13);

6) in methods of quantification of ligands to the GPCR protein of the present invention (pg 47, lines 13-15);

7) in a method of screening compounds that later the binding property between the GPCR protein of the present invention and ligands (pg 47, lines 15-19);

8) prophylactic and/or therapeutic agents for various diseases comprising a compound that alters the binding property between the GPCR protein of the present invention and ligands (pg 47, lines 19-23);

9) quantification of the receptor protein of the present invention, its partial peptides or salts thereof (pg 47, lines 23-25);

10) in methods of screening compounds that alter the amount of the receptor protein of the present invention or it partial peptides in cell membranes (pg 47, lines 25-28);

11) prophylactic and/or therapeutic agents for various diseases comprising a compound that alters the amount of the receptor protein of the present invention or its partial peptides in cell membranes (pg 47, lines 28-32);

12) neutralization by antibodies to the receptor protein of the present invention, its partial peptides, or salts thereof (pg 47, lines 32-34);

13) preparation of non-human animals that possess the DNA encoding the GPCR protein of the present invention (pg 47, line 34- 48, line 2);

14) preparation of antibodies (pg 111, lines 21-22);

15) construction of recombinant receptor protein expression systems (pg 111, lines 22-23);

16) development of receptor binding assay systems using the expression systems and screening of pharmaceutical candidate compounds (pg 111, lines 23-26);

17) effecting drug design based on comparison with structurally similar ligand receptors (pg 111, lines 26-27);

18) as reagents for preparation of probes and PCR primers for gene diagnosis (pg 111, lines 27-29); and

19) pharmaceutical drugs for gene prophylaxis and gene therapy (pg 111, lines 30-31).

These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed protein and DNA, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed GPCR protein or partial peptides, which is insufficient to meet the requirement of 35 USC § 101.

These activities and functions are conjectural and are based solely on the identification of SEQ ID NO:1 as being a G-protein coupled receptor (GPCR). While it is credible that SEQ ID NO:1 is a GPCR, its identification as such is not sufficient to establish either a well known, or a specific, substantial and credible utility. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. The use of an orphan receptor to discover its ligand or properties does not constitute a specific, substantial utility. Since the instant specification does not disclose how to use the polypeptide of SEQ ID NO:1, a skilled artisan would not know how to use nucleic acids encoding the polypeptide.

The art teaches that the GPCR family is extremely diverse, and that function cannot be predicted merely by identifying a protein as a GPCR. For example, Ji et al., in the Journal of Biological Chemistry 273(28): 17299-17302, teach that there have been nearly 2000 GPCR's reported, which are classifiable into 100 sub families according to sequence homology, ligand structure and receptor function. They further teach that different GPCR superfamily members are capable of sending signals via alternative signal molecules such as Jak2, phospholipase C, or protein kinase C, and that there are other seven transmembrane domain molecules that are not coupled to G proteins at all. Marchese et al. (Genomics 29:335), teach that IL-8 receptor, neuropeptide Y receptor and Somatostatin receptors are all GPCR's. Thus, although the homology of the GPCR family, especially in the transmembrane domain regions, allows identification of such as both GPCRs and as being evolutionarily related, such is not predictive of function. It is possible that, after further characterization, this protein might be found to have

a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease.

In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:1 or the polynucleotide encoding it (SEQ ID NO:2, the claimed invention is incomplete.

Claims 1-8, 14, and 19-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

Furthermore, even if the protein of SEQ ID NO:1 or the DNA of SEQ ID NO:2 that encodes SEQ ID NO:1 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

Claim 1 recites a protein which comprises the same or substantially the same amino acid sequence as SEQ ID NO:1, whereas claim 2 recites a partial peptide of the protein of claim 1 with no requirement for conserved structure or function. Claims 3, 4, 19, and 20 recite a DNA that encodes the protein of claim 1 or hybridizes to the DNA encoding the protein of claim 1 or is complementary to the polynucleotide that encodes the protein. However, other than the protein of SEQ ID NO:1 and the DNA of SEQ ID NO:2 that encodes the protein, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of SEQ ID NO:1 or SEQ ID NO:2 are critical to the activity of the protein of SEQ ID NO:1 (which is itself unknown); (2) what modifications (e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:1 that will result in protein mutants with the same activity as the protein of SEQ ID NO:1 or are "substantially the same" as SEQ ID NO:1; and (3) any guidance on how to use partial peptides of SEQ ID NO:1 which would, based on the language of said claims, encompass both active and inactive variants of SEQ ID NO:1. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions (See Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., The Protein Folding Problem and Tertiary Structure Prediction, 1994, pp. 492-495).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of substitutions/deletions on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 1-8, 14, and 19-20 are also rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was files, had possession of the claimed invention.

The specification discloses a protein of SEQ ID NO:1 and a nucleic acid sequence of SEQ ID NO:2 that encodes the protein of SEQ ID NO:1. However, claims 1 and 2 recite the protein of SEQ ID NO:1 and its homologues and fragments, whereas claims 3, 4, 19, and 20 recite a DNA that encodes the protein of claim 1 or hybridizes to the DNA encoding the protein of claim 1 or is complementary to the polynucleotide that encodes SEQ ID NO:1. Claims 5-8 and 14 depend, either directly or indirectly, from claim 1. The claims do not require that the proteins and nucleic acids possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of protein and its homologues or a genus of DNA molecules.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in claim 1 and 2 is a partial structure in the form of a recitation of "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1". The specification asserts that the "substantially the same amino acid sequences includes an amino acid sequence having at least about 50% homology, preferably at least 70% homology, more preferably at least 80% homology ..." (See page 15, lines 21-28 for example). Furthermore, the only factor present in claim 19 is a mere chemical property of the DNA in the form of a recitation of hybridizes to the polynucleotide encoding the protein of SEQ ID NO:1 or its homologues. The specification does not identify any particular structure/function correlation or biological activity. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is an amino acid sequence represented by SEQ ID NO:1 and a polypeptide encoded by SEQ ID NO: 2. Accordingly, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the protein of SEQ ID NO:1 and the DNA encoding the protein (SEQ ID NO:2), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### *Claim Rejections - 35 USC § 112, 2nd paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 14, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites the term "substantially the same". Since neither the art nor the specification provides an unambiguous definition of the term, the claim is indefinite.

Claim 2 is indefinite for reciting "a partial peptide". Without knowing the minimum length of the "partial peptide", the metes and bounds of the claim cannot be determined.

Claim 7 is rejected as being indefinite because it is not clear whether the limitation "a transformant" of claim 7 is intended to indicate an isolated cell, a transgenic animal, or a human.

Claim 8 is rejected as being indefinite because it is not clear whether the limitation "accumulating" is intended to indicate a method step, and if so, what are the steps; or it is an inherent property of the transformant.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as omitting any method steps. See MPEP § 2172.01. "Using" the protein according to claim 1 for determining a ligand does not set forth any steps involved in the method/process, therefore it is unclear what method/process is encompassed by the claim.

Claim 19 is rejected as being indefinite as there is no limiting definition of stringent hybridization conditions in the Specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. The discussion of such at page 28 of the Specification is noted but vague, fails to breathe life and

meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite.

Claim 20 is indefinite because it recites the term "or a part of ". Since neither the art nor the specification provides an unambiguous definition of the term "part", the claim is indefinite.

Claim 20 recites the limitation "a part of the base sequence" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 2-8 depend, either directly or indirectly, from claim 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 14, and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2003/0166148 A1, published on September 4, 2003; priority date, October 13, 1998).

Chen et al. teach a human G protein coupled receptor (GPCR) with an amino acid sequence that is 100% identical to SEQ ID NO:1 (See SEQ ID NO:40) and the cDNA that

encodes the receptor protein. This cDNA, which is 100% identical to SEQ ID NO:2, would also hybridize to SEQ ID NO:2 (See SEQ ID NO:39). Chen et al. also teach a vector and a host cell comprising the cDNA that encodes the receptor protein, a method of producing the receptor protein (see, for example, claims 79-80, Example 3), as well as a method of producing "partial peptides" utilizing site-directed mutagenesis (see Example 2, page 12). Finally, Chen et al. teach methods of identifying ligands (agonists and antagonists) to the receptor protein (see Example 7, pages 20-21, Figure 12). Thus, the reference of Chen et al. meets all the limitations of claims 1-8, 14, and 19-20.

***Summary***

Claims 1-8, 14, and 19-20 are hereby rejected.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
July 21, 2004

LORRAINE SPECTOR
PRIMARY EXAMINER